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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,873

12/08/2003

Paul McGlynn

00324/US1

1167

24330

7590

03/22/2007

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UNITED KINGDOM

EXAMINER

PUTTLITZ, KARL J

ART UNIT

PAPER NUMBER

1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/728,873

Applicant(s)

MCGLYNN ET AL.

Examiner

Karl J. Puttlitz

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-20, 24 and 27-29 is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☒ Claim(s) 25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

KARL PUTTLITZ
PATENT EXAMINER

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The rejection under section 112, first paragraph is withdrawn since the specification teaches preparation of levalbuterol L-tartrate in crystalline form.

The rejection under section 103 is withdrawn since the references does not particularly suggest the L-tartrate salts of levalbuterol. In this regard, common salts of pharmaceutical products would have been within the motivation and skill of those of ordinary skill, and thus prima facie obvious. In this connection, the examiner mentions the art of record and Berge et al., Journal of Pharmaceuticals 66(1) (1977), which demonstrates the common salts: hydrochloride, sulfate and tartrate (see table I on page 2). However, the Declaration under Rule 1.132 shows that tartrate salts, as opposed to the sulfates, and hydrochloride salts (shown in the specification), could not be formed into micronized pellets, suitable for administration with a metered does inhaler. However, the L-tartrate salts of levalbuterol could unexpectedly be micronized, and be suitable administered via a metered-does inhaler. Therefore, the showing under Rule 1.132 shows unexpected results of the L-tartrate salts, and thus, overcomes the prima facie case.

An updated search of the prior art failed to uncover a reference that teaches levalbuterol L-tartrate. The search also failed to uncover a reference that would have motivated those of ordinary skill to modify a know compound to provide the levalbuterol L-tartrate of the instant claims. In this regard, CN 1382685 teaches the tartrate salt of levalbuterol, see attached CAS online citation [retrieved March 16, 2007] from STN,

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Columbus, OH, USA. However, the Declaration under Rule 1.131 dated 7/3/2006 shows a reduction of practice in March 2002, which antedates this reference.

Claims 15, 16 and 18-29 are rejoined under MPEP 821.04(a). In this regard, the following objections and rejections are now entered:

Claim Objections

Claims 26 and 26 objected to because of the following informalities: the term "whenever" should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


Claims 21 recites preparation of levalbuterol L-tartrate by hydrogenation of R-benzylalbuterol. However, it is unclear how the L-tartrate salt is prepared in this manner. Moreover, claim 21 depends on claim 18, and in this manner it is unclear how hydrogenation integrates with the mixing of levalbuterol with tartaric acid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KARL PUTTLITZ
PATENT EXAMINER
3/16/07